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FDA O-T-C Testimony
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My name is Beverly Winikoff. I am a public health physician, and I am Program Director of Reproductive Health for the Population Council, a research and technical assistance organization that works internationally and domestically on problems of population, women's reproductive health, and technology development. As such, the Council has participated in the development of over half a dozen FDA approved drugs and devices and has additional pending applications with the FDA.

Our institutional and professional experience in developing products for use in fertility regulation and other aspects of reproductive health has provided the opportunity to think carefully about the issues involved in classifying drugs for safe and effective over the counter use.

Prescription status is reserved for products that are not safe for use, except under the supervision of a licensed practitioner. I would like to discuss seven criteria that seem particularly important in designating a product as appropriate for non-prescription or over-the-counter distribution. Then I will apply each of these criteria to hormonal contraceptives to make the case that these products should be available over-the-counter, probably generally but at least for certain indications and under certain conditions.

A drug sold without prescription should meet the following criteria:

1. Be non-addictive;
2. Have an indication use that is self-diagnosable;
3. Have a recommended regimen that is easy to comprehend and execute;
4. Have low likelihood of substantial incorrect use;
5. Have low potential for harm in the case of incorrect use;
6. Have mild side effects that are also largely self-diagnosable; and
7. Be more effective if obtained quickly.

All oral contraceptives generally meet all of these tests, whatever the specific situation.

1. **The drugs themselves are non-addictive** when used either as ongoing contraception or for the indication of emergency contraception in the event of unprotected sexual intercourse.
2. **The indication is quintessentially self-diagnosable.** A woman – and few others – knows she has had unprotected intercourse, in the case of emergency contraception, or desires to delay or avoid pregnancy in the case of ongoing contraception.
3. **The regimens are easy.** All the regimens for ongoing contraception involve taking one pill a day, sometimes continuously and sometimes with a break of seven days. Emergency contraception regimens involve taking two doses of pills (either one or two pills each dose), twelve hours apart and then stopping. It is hardly likely that American women who can prepare a TV dinner or use a walkman radio would be unable to understand such directions. A label

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appropriate for all patients and having passed appropriate label comprehension studies would be easy to prepare for such straightforward regimens.

4. ***It is unlikely to use these pills incorrectly.*** In other words, it is unlikely that a woman would take an entire pack of pills with her afternoon tea in the thought that this would be more likely to prevent pregnancy than following the package directions. The most common error would be to forget to take a pill, but this just reduces the possible efficacy of the method. It does not cause any medical problems. And there is no evidence that getting a prescription for such a medication reduces the likelihood that a person will forget a pill.
5. ***There is low potential for harm if used incorrectly.*** As above, even if a woman were to take more pills than directed, there is virtually no recorded toxicity from over-dosage. It is impossible to commit suicide with these pills, for example, or to abort or damage a fetus if a woman takes them if she is already pregnant. And the potential for harm relates merely to the lack of efficacy that would occur if ongoing contraceptives were taken sporadically or to the potential loss of efficacy if emergency contraceptives were taken in one dose only rather than two.
6. ***Side effects are mild for most of these medications.*** Serious effects are exceedingly rare and most such side effects, such as breast tenderness, headache, etc, are self-diagnosable by the woman. She can then elect to discontinue treatment, to seek medical advice about management of side effects, or continue despite some personal discomforts.
7. Perhaps the most important aspect of all of these medications, given their exceptional safety profile, is that in every case, ***efficacy is time sensitive***. For a woman who wishes to avoid an unwanted pregnancy after unprotected sex, the evidence is now clear that the single most important message is to take emergency contraception as soon as possible. Anything that delays access to the pills decreases the efficacy of the treatment. Prescription status would delay the access of every woman who wanted to take these pills to the medication unless she already had it in her medicine cabinet. There is no question that over the counter status would allow women a more effective remedy for a problem that she herself diagnoses and for which there are essentially no medical contraindications. In some respects, it is frankly illogical to make such a medication dependent on a visit or even a phone call to an open doctor's office or clinic before a woman can have access to these pills.

Similarly, in the case for ongoing contraception, women want effective protection as soon as possible after they have decided on it. And while it may be reasonable to expect a woman to be able to wait to start her pills, once she has started, she is often faced with a situation in which she may need a refill before she can get to a clinician. It is absolutely illogical to require a woman to get a prescription to replace a lost or destroyed pack of pills during a month in which she is taking that medication, or even to need to get to a practitioner before being able to replenish her pill supply, if she is an ongoing pill user. At the very least, women who are pill users should be able to reorder, replenish, and resupply themselves without needing additional medical prescriptions. In fact, it is probably reasonable to allow ongoing oral contraception to be purchased over the counter by some

women while it remains a prescription item for those women who choose to seek medical counsel before embarking on a regimen of oral contraception.

With respect to oral contraceptives, the FDA must face an important reality: making these drugs more accessible more immediately also makes them more effective. American women deserve indeed, require, easy, over-the-counter access to these important adjuncts to health, self-care and peace of mind.

Thank you.